United States Court of Appeals

for the Second Circuit

APPELLEE'S BRIEF

4-21

ORIGINAL

75-7122

To be argued by
DAVID W. FISHER

United States Court of Appeals
For the Second Circuit

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other person similarly situated,

Plaintiffs-Appellants,

v.

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, Health Services Administraiton; HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York, CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education, and Welfare of the United Staets of America,

Defendants-Appellees.

ON APPEAL FROM AN ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF OF APPELLEES: JOSEPH CIMINO, M.D., INDIVIDUALLY AND AS COMMISSIONER OF THE DEPARTMENT OF HEALTH OF THE CITY OF NEW YORK; THE DEPARTMENT OF HEALTH OF THE CITY OF NEW YORK; THE BOARD OF HEALTH OF THE CITY OF NEW YORK; GORDON CHASE, INDIVIDUALLY AND AS ADMINISTRATOR OF THE HEALTH SERVICES ADMINISTRATION, AND THE HEALTH SERVICES ADMINISTRATION

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Statement

This class action was commenced by the filing of a complaint and issuing of a summons on May 22, 1973, seeking declaratory and injunctive relief and monetary damages. The plaintiffs-appellants, who are non-physician self-

employed clinical laboratory directors in the City and State of New York, bring this action on behalf of themselves and all others similarly situated against the City, State and Federal Governments. Appellants have not perfected their class action pursuant to the court rules. The appellants claim that their rights under the Fifth and Thirteenth Amendments and the due process and equal protection clauses of the Fourteenth Amendment to the U. S. Constitution have been violated by the implementation of provisions of the City's Health Code and the State Public Health Law.

The City and State defendants answered and moved for summary judgment or for judgment on the pleadings. A hearing was held on October 21, 1974 before Hon. Dudley B. Bonsal and the court, by order dated January 10, 1975, dismissed the complaint and granted judgment to the defendants on the pleadings.

Issues Presented

1. Does the City's regulation, which requires private clinical laboratories to perform proficiency tests in order to maintain their licenses, violate the Due Process Clause of the Fourteenth Amendment?
2. Do the City regulations, which apply to private clinical laboratories, but not to physicians treating their own patients, violate the laboratories' rights under the Equal Protection Clause of the Fourteenth Amendment?
3. Do the plaintiffs' claims show a substantial violation of their constitutional rights upon which federal jurisdiction may be founded?

Statutes Involved

New York City Health Code

§ 13.03(a) This article is applicable to all clinical laboratories operating within the limits of the City of New

York except a clinical laboratory maintained by the State of New York or the Government of the United States or by a licensed physician who performs tests referred to in Section 13.01, personally or through employees, solely in connection with the treatment of his own patients. However, a laboratory which makes such tests on its own responsibility for a physician is subject to the provisions of this article.

* * *

§ 13.25(d) A clinical laboratory shall at any time during its regular working hours permit the inspection of its premises, records, incubators, refrigerators, material and equipment by a representative of the Department and shall, for the purpose of determining its competence, examine all specimens submitted by the Department in the presence of a representative thereof and shall report promptly the results of such examination to the Department.

* * *

§ 13.25(f) A specimen received by a laboratory shall not be tested or reported on if:

(1) the apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested.

(2) it has been collected, labeled, preserved or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen.

(3) it is perishable and time lapse between the collection of the specimen and its receipt by the laboratory is of such duration that the test finding may no longer be reliable.

§ 13.25(g) When a specimen is not tested for any of the reasons specified in subsection (f) of this section the laboratory shall promptly notify the sender and give the reason therefor.

NEW YORK STATE PUBLIC HEALTH LAW

§ 570. **Declaration of policy and statement of purpose.** The proper performance of laboratory services is a matter of vital concern, affecting the public health, safety and welfare. Clinical laboratories and blood banks provide essential public health services in aiding the medical practitioner by furnishing information invaluable to the diagnosis and treatment of disease. The improper performance of a laboratory procedure may induce an erroneous diagnosis or contribute to the selection of an inappropriate method of treatment, resulting in prolonged or unnecessary hospitalization, injury or even death. The protection of the people of this state requires affirmative action to insure that the performance of laboratory and blood banking services meet high standards of public health care.

It is the purpose of this title to promote the public health, safety and welfare by requiring the licensure of clinical laboratories and blood banks, by establishing minimum qualifications for laboratory directors, and by requiring that the performance of all procedures employed by clinical laboratories and blood banks shall meet minimum standards accepted and approved by the department.

Facts

The Plaintiffs Complaint

The plaintiffs allege in their complaint that the City and State Health Departments require that the plaintiffs, in order to maintain their clinical laboratory licenses, perform proficiency testing on faulty, ill-prepared, faked or artificial specimens incapable of accurate testing. Plaintiffs allege that this type of testing requires them to expend great and unnecessary amounts of time and labor in using

their own material and equipment and, thus, is a seizure of property without compensation under color of state law and in violation of due process of law and the Thirteenth Amendment of the U. S. Constitution (A5).*

Plaintiffs further allege that the City denies them equal protection of the law because physicians are exempted from proficiency testing where physicians or their employees perform tests in their offices on their own patients (A6-A7). The plaintiffs also allege unequal enforcement of the laws, in that the City permits physicians to operate private clinical laboratories, testing specimens on referral from other sources without meeting the City's licensing requirements and without paying the "onerous" fees, and that this "completely unregulated practice of the clinical laboratory profession constitutes a threat to the public health and welfare and causes irreparable injury and damage to the plaintiffs who do not operate on an equal footing with practicing physician-operated laboratories." (A8)

Plaintiffs' demand a) $1,000,000 from each governmental body as fair value for the use of their labor, materials and equipment, b) that the defendants be enjoined from requiring the plaintiffs to perform any more proficiency testing, and c) that no one should be exempt from the conditions or requirements of operating laboratories (A12).

The City's Answer

The City of New York pursuant to state legislation, N. Y. Public Health Law §§ 572(2), 574(2), promulgated regulations for operating clinical laboratories within the City. Each clinical laboratory and its director must obtain permits authorizing the tests that it may perform. to main-

* The letter "A" before a number refers to pages in the Appendix. The letters "SA" before a number refers to pages in the Supplementary Appendix.

tain its license, each clinical laboratory must participate in a proficiency-testing program under which it is required to analyze specimens sent by the City's Health Department and to report the results which are then graded by the Health Department. A laboratory which repeatedly fails to perform sufficiently accurate tests can lose its permit. The Health Code provides that if a laboratory determines that a test specimen is defective or contaminated, it need only report that fact to the Health Department and it is excused from performing that test for that calendar period [N.Y.C. Health Code § 13.25(f)]. Of the named plaintiffs coming under its jurisdiction, on only two occasions was a report made of contaminated specimens and, in those cases, the laboratory was excused from that period's testing (SA-1, SA-11). Appellants do not allege that any laboratory or clinical director has lost its' license due to the proficiency testing requirements.

The New York City Health Code exempts licensed physicians and their employees who perform tests in connection with the treatment of their own patients from the licensing requirements, but does not exempt physicians who operate clinical laboratories.

The Decision Below

In the district court, Judge Bonsel granted the State and City defendants' motions for judgment on the pleadings, on the ground that the plaintiffs failed to state a substantial federal question upon which jurisdiction may be founded.

The district court found that the plaintiffs' due process claims were without merit. The court said that

> "The defendants' permit and proficiency testing programs are essential to protect the public from the consequences of incompetent clinical laboratory test-

> ing. To achieve this goal, it is appropriate that the State and City require clinical laboratories to obtain permits based upon proficiency tests. . . . There is also a rational basis for imposing these requirements upon clinical laboratories while exempting office connected laboratories directed by licensed physicians." (A86-A87)

The court also found that the plaintiffs' claims that their equal protection rights had been violated did not meet the equal protection tests set forth by the court[1] and therefore, did not state a substantial federal question. In regard to the rational basis test the court found that,

> "The distinction drawn by the State clearly passes this test for rationality. As with respect to the plaintiffs' due process claim, clinical laboratories have no contact with the patient aside from the specimen taken from his body. Therefore, there is greater possibility that erroneous laboratory results will go undetected than when an attending physician, who knows the patients symptoms and history obtains an inaccurate test result." (A88)

Additionally, with respect to the claim of non-enforcement of the regulations the district court found that since the plaintiffs had failed to allege that the City and State defendants had knowledge of the alleged violations, the plaintiffs had not alleged the elements necessary for a federal equal protection claim, i.e., that there was purposeful discrimination.

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1. "So long as the statutory distinction is rational and the statutory classification is based on criteria related to the objective of the statute or has some basis in practical experience, there is no violation of the equal protection clause . . . (citations omitted)." (A88)

Accordingly, the Court found that the plaintiffs could not claim jurisdiction under 28 U.S.C. § 1343 and referred the plaintiffs to the administrative agencies or the State courts for a redress of their grievances.

> "To confer subject matter jurisdiction under section 1343, plaintiffs complaint must state a constitutional claim 'of sufficient substance to support federal jurisdiction.' *Hagens* v. *Lavine* 415 U.S. 528, 536 (1974). A claim is 'insubstantial' either because it is 'obviously without merit' or because 'its unsoundness so clearly results from the previous decisions . . . as to foreclose the subject and leave no room for the inference that the question sought to be raised can be the subject of controversy'. *Hagens* v. *Levine*, *supra* at 537, and cases cited therein." (A85-A86)

ARGUMENT

The plaintiffs have failed to state a substantial federal question upon which jurisdiction may be founded.

POINT I

The City's proficiency testing requirement for clinical laboratory licensing provides a valid and reasonable means of regulating private clinical laboratories and protecting the health of the citizenry. The requirements are validly enforced and have not resulted in the loss of license by any clinical laboratory but, rather, have upgraded their performance.

The City's laboratory improvement program is conducted pursuant to Article 13 of the New York City Health Code. This power stems from the authority granted by the State in Public Health Law Article 5, Section 572

(2), 574(2). The State Law was passed pursuant to the state's police power, and is a proper exercise of the police power as stated in Public Health Law § 570.

Public Health Law Article 5, Title 5 (Laws of 1964, Chapter 217) was passed in response to the Governor's annual message to the Legislature delivered on January 8, 1964 in which he stated:

> "The State Health Department reports shocking instances of incompetence on the part of clinical laboratories operating within the State. While laboratories provide essential services for the public and for the medical practitioner—furnishing information invaluable to the diagnosis and treatment of the disease—their improper performance of blood and other tests may result in prolonged and unnecessary hospitalization, injury and even death."

It is not contested that the City is not acting pursuant to statutes and ordinances of the City of New York, and no one can argue that the regulation of clinical laboratories which provide essential health services "is not a proper subject of the police power." See *Watson* v. *Maryland*, 118 U.S. 173 (1915). The requirement that a laboratory report the results of examinations of specimens submitted by the City for determining the laboratory's competence [N.Y.C. Health Code § 13.25(d) falls] within the guidelines and purposes of the Public Health Law and, therefore, the programs are well within the bounds of the state's police power. See *North Dakota State Board of Pharmacy* v. *Snyder's Drug Stores, Inc.*, 414 U.S. 156 (1973); *Williamson* v. *Lee Optical Co.*, 348 U.S. 483 (1955).

Appellants do not complain of being tested, but allege only that "they are tested in a faulty, arbitrary and abu-

sive way, and that this faulty and abusive test program deprives them of substantial property." (brief p. 14)

Reasonable regulations restricting the use of property in order to safeguard public health do not constitute a compensible appropriation of property for public use. *N. O. Public Service* v. *New Orleans*, 281 U.S. 682 (1930). The City's laboratory improvement program being reasonable, appellants must bear the cost, if any, of complying with the program's regulations. *N. O. Public Service, supra; Pent-R-Books, Inc.* v. *U. S. Postal Services*, 328 F. Supp. 297, 315 (E.D.N.Y. 1971), citing federal laws requiring an industry to pay the costs of complying with regulations established for testing its proficiency, 15 U.S.C. 78o(b) (8), (concerning the Securities and Exchange Commission), 12 U.S.C. 482 (concerning the expenses of examining national banks) and 7 U.S.C. § 2153 (the Animal Welfare Act).

The allegations in the complaint that the New York City Board of Health and The Department of Health of the City of New York delivered to the plaintiffs "faked or artificial specimens incapable of accurate testing including poor, stained, unreadable slides." (A5), raises no federal or constitutional issues. In fact, however, the New York City Health Code § 13.25(f),(g) provides that a laboratory *shall not* report on a specimen if it is unsuitable for testing or inappropriate for the testing requested, and that when a specimen is not tested for any reason specified in § 13.25(f), the laboratory shall notify the sender of the conditions. Thus, the regulations provide expeditious methods of dealing with a faulty specimen with no penalty to the laboratory. Certainly, in dealing with specimens, there is always a possibility of contamination no matter how great the safeguards are. On one occasion, the plaintiff Ronis returned a sample as being faulty (SA-1) and was excused from performing the test. Additionally, appellants' ex-

hibits contain a letter to plaintiff Friedlander excusing him from performing a test because a specimen was faulty (SA-11). Not only is the laboratory excused from performing that test but it is not required to make up that test (A29).

It should be noted that the average medicaid fees for performing all the required proficiency tests requested of each appellant by the City in 1972, was only $161.60 (A33). This amount includes profit, so that the cost would necessarily be less. When one considers the value of proficiency testing as a means of assuring the laboratories' competency and as a protection the public health and welfare, it cannot be said that the cost is at all unreasonable.

Appellants allegation (brief p. 9) that the Department of Health conducted experiments in the context of proficiency testing at appellants' expense, is without foundation, as is explained in the affidavit of Sylvia Blatt (A29). Laboratories had been given reagents to determine whether variations in prothrombin time tests resulted because laboratories used different reagents. This enabled the laboratories to obtain uniform results in an area where patients needed constant monitoring and different laboratories might have used different reagents. By giving the laboratories the reagents during that period, the laboratories were getting the benefit of the City's reagents and, therefore, did not have to use their own materials. Additionally, these were considered the proficiency tests for that calendar period. The City was thereby making double use of these tests.

The appellants complain that the City uses liquid rather than clotted blood in its blood typing tests. (brief p. 8). The Health Department now uses liquid blood for blood typing instead of clotted blood on a basis of the

consensus in the profession that this is preferred. The use of liquid or clotted blood is immaterial to the laboratories and the appellants appear to be grasping for straws.

The health, welfare and safety of the residents of the City is being protected by the City's proficiency testing. The affidavit of Sylvia Blatt clearly shows that improvement in competency and accuracy of the laboratories was enhanced by the proficiency testing procedure (A7 and Exhibits at SA-2-SA-6).

POINT II

The City regulations, which allow physicians to perform clinical tests on their patients, while exempting them from the licensing and proficiency testing required of private clinical laboratories, are based on the valid distinction which exists between a physician and his patient and the private laboratory and its customer, and are not arbitrary and unresonable.

The thrust of the appellants equal protection arguments appears to be that the City has created an unreasonable class distinction in favor of physicians performing tests on their own patients and in favor of consulting physicians who perform tests on their referral patients.

Clearly, the appellees do not violate the equal protection rights of appellants. The burden of proof of showing a violation of equal protection falls on the one who attacks the constitutionality of a class distinction to demonstrate that it is unreasonable and arbitrary. *Morey* v. *Doud*, 354 U.S. 457 (1957); *Lindsley* v. *Natural Carbonic Gas Co.*, 220 U.S. 61, 78-79 (1911).

So long as the statutory distinction is rational and a class distinction is based on criteria related to the objective of the statute, or is based on some practical experience,

there is no violation of the equal protection clause. See *San Antonio School District* v. *Rodrigues*, 411 U.S. 1, 40 (1973); *McGinnis* v. *Royster*, 410 U.S. 263, 276 (1973).

The declaration of policy found in Public Health Law § 570 indicated that Title 5 was enacted in response to the Governor's message and Health Department reports of inaccurate testing and reporting by clinical laboratories. There is no mention in the report of incompetency on the part of physicians in performing tests in the treatment of their own patients, so that drawing a distinction between a clinical laboratory, and physicians testing their own patients cannot be said to be unreasonable. It is reasonable for the government to regulate a field where experience shows an evil to exist without trying to regulate the entire field and eliminate all possible abuses. To obtain these objectives the legislature may move one step at a time. *Schild* v. *Kuebel*, 404 U.S, 357, 364 (1971); *Williams* v. *Lee Optical, supra; Radice* v. *New York*, 264 U.S. 292, 297 (1924). In *Derman* v. *Ingraham*, 47 Misc. 2d 346 (Sup. Ct. Ulster Co., 1965), affd. 23 AD 2d 795 (3rd Dept., 1966) mot. for leave to appl. den. 18 NY 2d 579 (1966), licensed physicians (pathologists) argued that the law which requires them to meet the qualifications of clinical laboratories when testing for other physicians, was violative of their equal protection rights because they did not have to qualify if they were treating their own patients. The Court held that there was a valid class distinction between a physician treating his own patient and when he tested for another physician.

It is obvious that the distinction between a physician performing a test in his treatment of his own patient and anyone, physician or non-physician, performing tests on others is valid. The clinical laboratories' only relation to the patient is the specimen taken from his body. The person performing the test, in such a case, does not have

access to the patient's medical history and cannot, therefore, relate the results of the laboratories' test to the condition of the patient being tested. A physician, knowing the patient, can be alerted to results that are out of line with his medical history and retest the patient if necessary. Appellants' argument that physicians can make mistakes belabors the obvious and, needless to say, as shown by the records of clinical laboratories, they are far from perfect themselves. Further, the physician is already duly licensed by the State, whereas the clinical laboratories, absent these regulations, would be unsupervised.

Plaintiffs' other allegations are that the State and City defendants have been informed of alleged violations of their regulations and have failed to correct these abuses, and, more specifically, that the defendants permit physicians to operate private laboratories without complying with licensing and testing requirements. These allegations, as shown by the affidavits of Sylvia Blatt (A26-A27 and A77-A80) are without substance. The City defendants have always enforced the City's regulations relating to the operation of clinical laboratories and require that physicians must have clinical laboratory licenses when they perform tests on other than their own patients.

Assuming *arguendo* that the City may have been remiss or negligent in the enforcement of its regulations this is certainly not enough to raise a constitutional issue as to the equal protection due under the Fourteenth Amendment, *Oyler* v. *Boles*, 368 U.S. 448, 456 (1962). There must be shown to have existed an element of intentional or purposeful discrimination, and discriminatory purpose is not presumed. *Snowden* v. *Hughes*, 32 U.S. 1, 8 (1944). The prohibition of the equal protection clause goes no further than invidious discrimination, *Williams* v. *Lee Optical*, 348 U.S. 483, 489 (1955). The appellants have completely failed to show denial of their equal protection rights.

The affidavits, exhibits and arguments propounded by the appellants in support of their position merely expresses a strong conviction against the challenged wisdom and efficacy of the legislation in issue, neither of which is germane to the issue of constitutionality. As the Supreme Court stated in *Ferguson* v. *Skrupa*, 372 U.S. 726, 731 (1963):

> "... we refuse to act as a super legislature to weigh the wisdom of the legislation. . . . The statute may be wise or unwise, but relief, if any be needed, lies not with us but with the body constituted to pass laws for the State ..."

CONCLUSION

Since the City's method of regulating its clinical laboratories does not violate the equal protection or due process rights of the appellants, the decision of the District Court should be affirmed and the complaint dismissed for failure to raise a substantial federal question.

Dated: New York, New York
April 18, 1975

Respectfully submitted,

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State of New York, County of New York, ss.: James J. Ballard

being duly sworn, says, that on the 21 day of April 19 75

at No. Ag Court House. 10704 500 Pearl in the Borough of Man in The City of New York, he served ~~three~~ Two copies

of the annexed Brief upon Paul Curran Esq.,

the attorney for the U.S. Court House in the within entitled action by delivering

three copies of the same to a person in charge of said attorney's office during the absence of said attorney therefrom, and leaving the same with him.

Sworn to before me, this 21 day of April 19 75

James J. Ballard

DAVID W. FISHLOW
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No. 24-1229615 Qualified in Kings Co.
Commission Expires March 30, 19

Jacobs

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Bruce Garner

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Notary Public, State of New York
No. 24-1229610 Qualified in Kings Co.
Commission Expires March 30, 19??

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Joel Eppel

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three copies of the same to a person in charge of said attorney's office during the absence of said attorney therefrom, and

leaving the same with him.

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Joel Eppel

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DAVID W. FISHER
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Commission Expires March 30, 1977